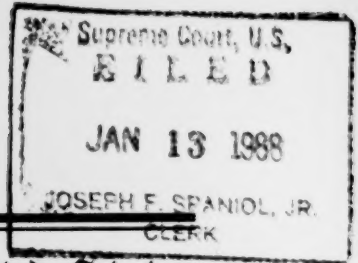


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No.



In the Supreme Court of the United States

OCTOBER TERM, 1987

UNITED STATES OF AMERICA, PETITIONER

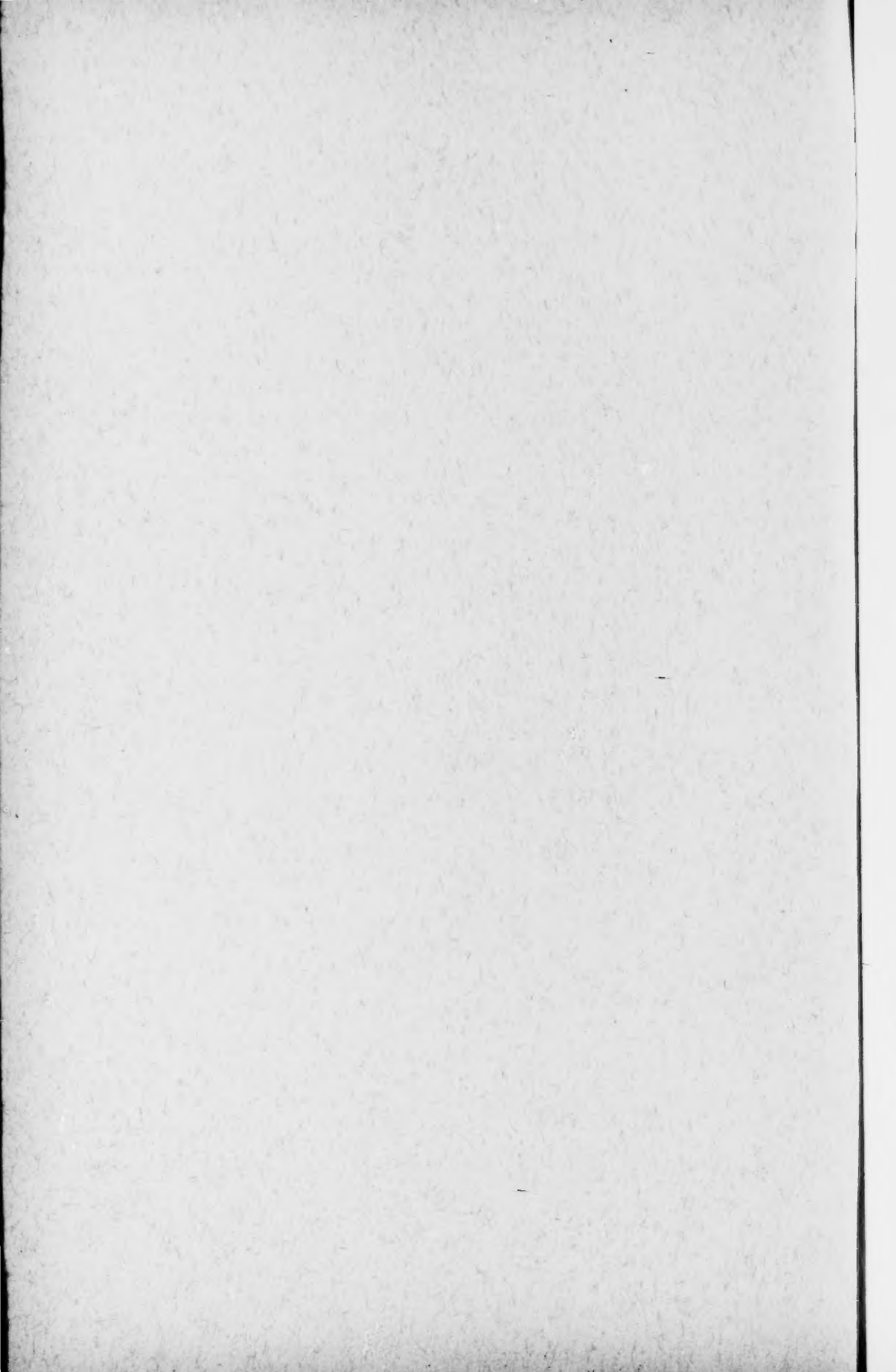
v.

WADE BAKER, ET AL.

**PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

CHARLES FRIED
Solicitor General
Department of Justice
Washington, D.C. 20530
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1472



QUESTION PRESENTED

Whether the discretionary function exception to the Federal Tort Claims Act, 28 U.S.C. 2680(a), bars respondents' claim that the government was negligent in its 1963 decision to license Lederle Laboratories' Sabin oral polio vaccine.



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In the Supreme Court of the United States

OCTOBER TERM, 1987

No.

UNITED STATES OF AMERICA, PETITIONER

v.

WADE BAKER, ET AL.

**PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

The Solicitor General, on behalf of the United States of America, petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-13a) is reported at 817 F.2d 560. The opinion of the district court (App., *infra*, 14a-15a) is unreported.

JURISDICTION

The decision of the court of appeals was entered on May 18, 1987. A petition for rehearing with suggestion of rehearing en banc was denied on October 15, 1987 (App., *infra*, 16a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Respondent Wade Baker contracted poliomyelitis from his nephew, who had recently been innoculated with Orimune, a Sabin oral polio vaccine manufactured by

Lederle Laboratories. This vaccine contains a "shed virus" that spreads to, and generally immunizes, those who come into close contact with the vaccinated person. App., *infra*, 2a. Baker and his wife filed suit in federal district court alleging that the United States is liable for his injuries under the Federal Tort Claims Act (FTCA) because the government was negligent in licensing Orimune on June 25, 1963. Respondents claimed that the Department of Health, Education and Welfare (HEW (now the Department of Health and Human Services)) had negligently failed to follow its own regulations in supervising Lederle's testing of the vaccine prior to licensing. Specifically, respondents alleged that HEW was negligent in failing (1) to require Lederle to test adequately the safety and effectiveness of the Sabin poliovirus strain prior to licensing in 1963; (2) to require Lederle to test adequately the vaccine itself prior to licensing in 1963; and (3) to require Lederle to test the shed virus for safety and efficacy and to obtain a license for its manufacture. App., *infra*, 2a-3a.

2. The government moved to dismiss the suit as barred by the discretionary function exception to liability under the FTCA, 28 U.S.C. 2680(a). The district court granted the motion, holding (App., *infra*, 14a) that "the present case is analogous to *United States v. S.A. Empresa de Viacao Aerea Rio Grandense (Varig Airlines)*, [467 U.S. 797 (1984),] and is therefore barred by the discretionary function exception to the Federal Tort Claims Act." The court of appeals reversed (App., *infra*, 1a-13a), relying in part on two pre-*Varig Airlines* cases, *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974) and *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981), cert. denied, 456 U.S. 944 (1982). The court distinguished *Varig Airlines*, where "the mandatory regulations governed the conduct of the airline, not the government" (App., *infra*, 12a). It said that in this case, by contrast, the agency "may not issue a license for manufacturing poliovirus vaccine unless

the relevant test data has been submitted," and that the agency thus has a mandatory duty to require the submission of those data (*ibid.*). While acknowledging that "[t]he issue * * * pose[d] is a close and difficult one" (*id.* at 9a), the court stated that it was unwilling to apply the discretionary function exception to respondents' allegations of "a negligent failure to obey a mandatory regulatory command" (*id.* at 12a).

REASONS FOR GRANTING THE PETITION

There is a direct conflict between the decision of the court of appeals and a recent decision by the Third Circuit in *Berkovitz v. United States*, 822 F.2d 1322 (1987), cert. granted, No. 87-498 (Jan. 11, 1988). Because of this conflict and of the importance of the question presented, we acquiesced in the petition for certiorari filed in *Berkovitz*. The instant case should accordingly be held for disposition as appropriate in light of the decision in *Berkovitz*.

On June 30, 1987, just over a month after the court of appeals' decision in this case, a divided panel of the Third Circuit held in *Berkovitz* that the discretionary function exception does apply to the government's 1963 decision to license the Lederle oral polio vaccine. The plaintiffs in *Berkovitz* alleged that the government issued a license for Lederle's Sabin poliovirus strain when it had not been subjected to all required testing and did not comply with all regulatory standards (822 F.2d at 1324). The court of appeals stated that the question presented was whether the government had a nondiscretionary duty to ensure that Lederle followed regulatory standards in the production and distribution of the Sabin polio vaccine (*id.* at 1329). The court of appeals canvassed the applicable regulations and noted that, while they required the manufacturer to perform certain tests and submit qualifying results to the government, they did not require the government to do anything (*id.* at 1329-1332). The court concluded that, as

in *Varig Airlines*, the onus was on the manufacturer to comply with applicable safety standards, while the role of the government agency was “ ‘merely to police the conduct of private individuals by monitoring their compliance with [the applicable] regulations’ ” (*id.* at 1332 (quoting 467 U.S. at 815)). Because “neither the statute nor the regulations mandate the [agency’s] choice of how to secure Lederle’s compliance” (822 F.2d at 1332), the court concluded that the discretionary function exception bars suit for alleged negligence in the government’s performance of that role.

There is, thus, a direct conflict between the Ninth Circuit’s holding in this case that the government’s decision to license the Sabin vaccine was not a discretionary function, and the Third Circuit’s decision in *Berkovitz* that it was.¹ In light of this conflict and the importance of the question presented, we acquiesced in the petition for certiorari filed by the plaintiffs in *Berkovitz*.² The Court has now granted certiorari in *Berkovitz*. We therefore suggest that the Court hold this case pending a decision on the merits in *Berkovitz*.

¹ In *Berkovitz*, the court of appeals noted the decision in this case and stated that “Berkovitz’s complaint can be read as alleging a similar failure to require submission of test data.” The Third Circuit expressly declined to follow the Ninth Circuit panel’s determination on this issue, stating (822 F.2d at 1330 n.6):

We do not agree, however, that the [agency] is under a duty to require submission of test data. Rather, the duty to submit test data rests with the manufacturer. See 21 C.F.R. §§ 601.2, 610.1, 630.10(b)(4) (1987).

² We have furnished respondents with a copy of our acquiescence in *Berkovitz* and will furnish petitioners in that case with a copy of the instant petition.

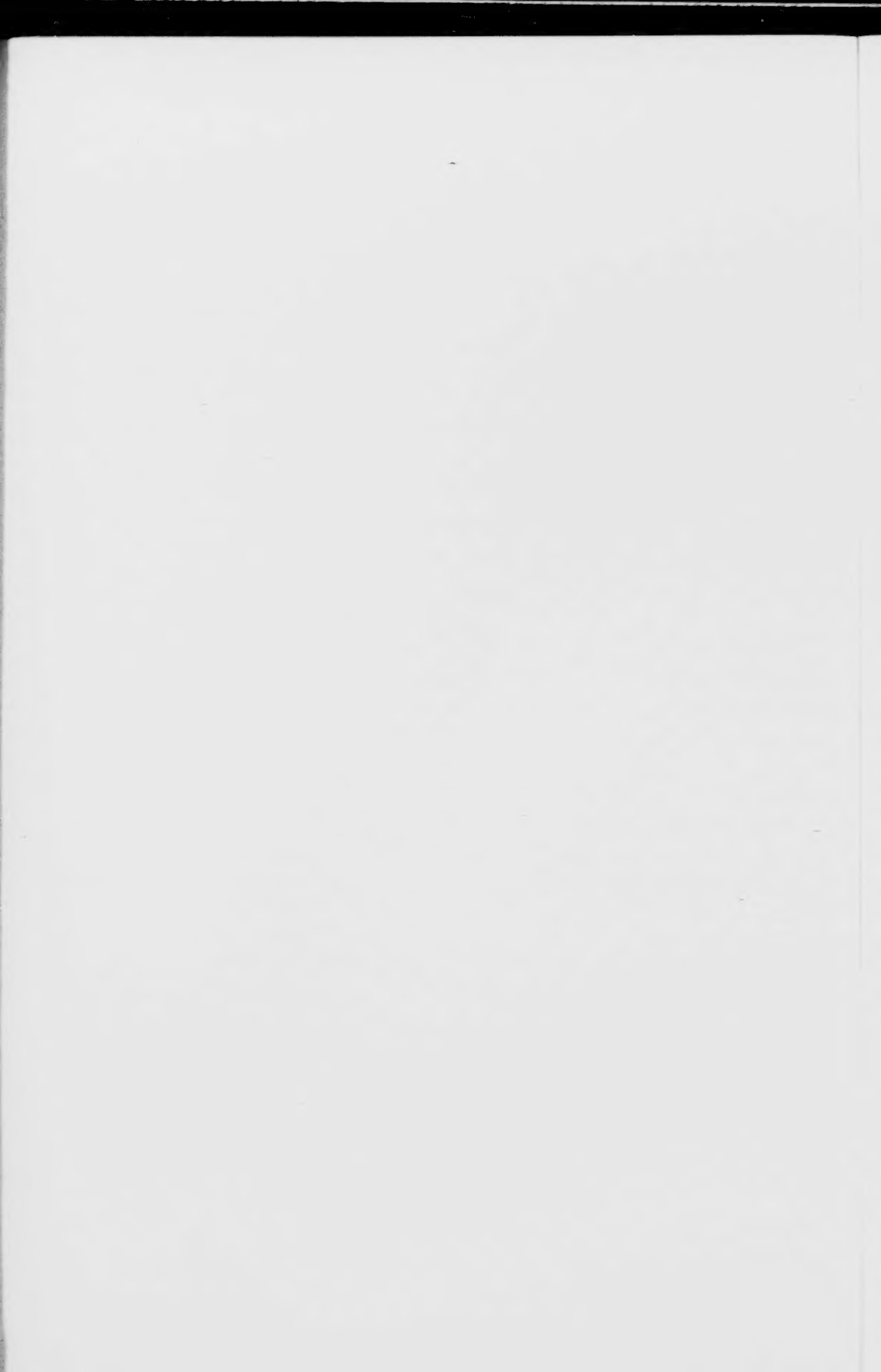
CONCLUSION

The petition for a writ of certiorari should be held and disposed of as appropriate in light of the decision in *Berkovitz v. United States*, cert. granted, No. 87-498 (Jan. 11, 1988).

Respectfully submitted.

CHARLES FRIED
Solicitor General

JANUARY 1988



APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 86-5578

D.C. No. CV85-04704-HBT

WADE BAKER AND RITA BAKER, PLAINTIFFS-APPELLANTS

v.

UNITED STATES OF AMERICA, DEFENDANT-APPELLEE

Appeal from the United States District Court
for the Southern District of California

Argued and Submitted
December 4, 1986—Pasadena, California

Filed May 18, 1987

Opinion by Judge SNEED

Before: JOSEPH T. SNEED and MARY M. SCHROEDER, Circuit Judges, and ALFREDO C. MARQUEZ,* District Judge.

* Honorable Alfredo C. Marquez, United States District Judge, District of Arizona, sitting by designation.

OPINION

SNEED, Circuit Judge:

Appellants, Wade Baker and Rita Baker, brought this action against the United States under the provisions of the Federal Tort Claims Act (FTCA), 28 U.S.C. §§ 1346(b), 2671 *et seq.* The appellants allege that Wade Baker's contraction of poliomyelitis was caused by the negligence of the United States Department of Health, Education and Welfare (HEW),¹ which had licensed the vaccine in question for marketing by Lederle Laboratories. The district court dismissed the action for lack of subject matter jurisdiction, ruling that the action was barred by the discretionary function exception to the FTCA. We reverse.

I.

FACTS

In June 1963, the Secretary of HEW licensed Lederle Laboratories to manufacture a trivalent, live, oral poliovirus vaccine (Vaccine). The Vaccine is composed of all three Sabin strains of live poliovirus corresponding to the three different types of polio and therefore is called "trivalent." A characteristic of live Sabin polio vaccine is that not only is the vaccine's recipient immunized from polio, but unimmunized persons who come into close contact with the vaccinated person also may be immunized through a "shed virus" that spreads from the person vaccinated to the person in close contact. Because Sabin strains contain the live polio virus, either or both persons could develop polio. Consequently, the Secretary has promulgated regulations pertaining to safety, purity, and potency standards that serve to protect susceptible persons

¹ This department has been redesignated the Department of Health and Human Services. 20 U.S.C. § 3508(a).

from contracting the disease. *See* 21 C.F.R. §§ 630.10-.17.² Drug manufacturers must establish their product's conformity to these regulations before the Secretary will issue a license for manufacturing. 42 U.S.C. § 262(d).

In November 1983, Wade Baker was exposed to the shed virus after a doctor had inoculated his infant nephew with the Vaccine only a month earlier. On November 12, 1983, Baker developed symptoms of vaccine-associated poliomyelitis and was hospitalized two weeks later. Baker has been permanently injured as a result of having contracted the disease.

On August 6, 1985, the appellants brought suit in district court against the United States and unknown employees of HEW. The gravamen of the complaint is that HEW failed to adhere to its own regulations in supervising the Lederle testing of the Vaccine. The three counts of the complaint allege that HEW was negligent in failing (1) to require Lederle to test adequately the safety and effectiveness of the Sabin poliovirus strain used to manufacture the Vaccine; (2) to require Lederle to test adequately the Vaccine itself prior to licensing; and (3) to require Lederle to obtain a license for manufacture of the shed virus and to test the shed virus for safety. The government filed a Motion to Dismiss or in the Alternative for Summary Judgment. The court granted the motion, finding that the plaintiff's claims were barred by the discretionary function exception to the FTCA. The Bakers timely filed this appeal.

II.

STANDARD OF REVIEW

The proper standard for review of a district court's determination that it lacks subject matter jurisdiction

² At the time of Lederle's licensing, these regulations were found at 42 C.F.R. § 73.110-.118.

under the discretionary function exception is *de novo*. *Chamberlin v. Isen*, 779 F.2d 522, 523 (9th Cir. 1985).

III.

DISCUSSION

The United States can be sued only to the extent that it has waived its sovereign immunity. *United States v. Orleans*, 425 U.S. 807, 814 (1976). A party bringing a cause of action against the federal government bears the burden of showing an unequivocal waiver of immunity. *Holloman v. Watt*, 708 F.2d 1399, 1401 (9th Cir. 1983), *cert. denied*, 466 U.S. 958 (1984). Thus, the United States may not be sued without its consent and the terms of such consent define the court's jurisdiction.

The Federal Tort Claims Act renders the United States liable for damages:

for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

28 U.S.C. § 1346(b).

The Act, however, does not waive the sovereign immunity of the United States in all cases. Several classes of tort claims are excepted from the Act's waiver of immunity. The "discretionary function exception," found in 28 U.S.C. § 2680(a), is the exception we must consider in this case. It exempts from the reach of the FTCA

[a]ny claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, *or based upon the*

exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

28 U.S.C. § 2680(a) (emphasis added).

The plaintiff in this case alleges the negligent failure of HEW to require the mandatory tests of 21 C.F.R. § 630.10(b)³ when Lederle was licensed to manufacture

³ 21 C.F.R. § 630.10(b) provides as follows:

Criteria for acceptable strains and acceptable seed virus. (1) Strains of attenuated poliovirus Types 1, 2, and 3 used in the manufacture of the vaccine shall be identified by: (i) Historical records including origin and techniques of attenuation, (ii) antigenic properties, (iii) neurovirulence for monkeys, (iv) pathogenicity for other animals and tissue cultures of various cell types, and (v) established virus markers including ret/40, d, and other markers shown to be associated with strain virulence.

(2) Poliovirus strains shall not be used in the manufacture of Poliovirus Vaccine Live Oral, unless, (i) data are submitted to the Director, Office of Biologics Research and Review which establish that each such strain is free of harmful effect upon administration in the recommended dosage to at least 1 million people susceptible to poliomyelitis, under circumstances where adequate epidemiological surveillance of neurological illness has been maintained, and; (ii) each such strain produces a vaccine meeting the safety and potency requirements of §§ 603.11, 630.15, and 630.16(b). Susceptibility shall be demonstrated by blood tests, stool examinations and other appropriate methods.

(3) Each seed virus used in manufacture shall be demonstrated to be free of extraneous microbial agents except for unavoidable bacteriophage.

(4) No seed virus shall be used for the manufacture of poliovirus vaccine unless its neurovirulence in Macaca monkeys is no greater than that of the Reference Attenuated Poliovirus distributed by the Office of Biologics Research and Review. The neurovirulence of the seed virus shall be demonstrated by the following tests to be performed by the manufacturer: (i) The test

live, oral poliovirus vaccine in 1963 for release to the public. Baker contends that the failure by the government to do what its own regulations command it to do is actionable under the FTCA.

The Supreme Court most recently addressed the discretionary function exception in *United States v. S.A. Empresa de Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797 (1984). The Court characterized the excep-

prescribed in § 630.16(b)(1) using seed virus as test material in place of monovalent virus pool material and (ii) the following comparative intramuscular neurovirulence test: Each of at least 10 monkeys shall be injected with a total of 5.0 ml. of the seed virus under test in one or more proximate locations of either a gluteus or gastrocnemius muscle. Similar injections shall be made in another group of 10 monkeys using the Reference Attenuated Poliovirus. Each monkey shall be injected intramuscularly with no less than $10^{7.7}$ TCID₅₀ of viral inoculum. All monkeys shall be observed for 17 to 21 days and a comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the Reference Attenuated Poliovirus, as prescribed in § 630.16(b)(1)(iii).

(5) Subsequent and identical neurovirulence tests shall be performed in monkeys whenever there is evidence of a change in the neurovirulence of the production virus, upon introduction of a new production seed lot, and as often as necessary otherwise to establish to the satisfaction of the Director, Office of Biologics Research and Review that the seed virus strains for vaccine manufacture have maintained their neurovirulence properties as set forth in § 630.16(b)(1)(iii).

(6) The Director, Office of Biologics Research and Review, may, from time to time, prohibit the use of a specified strain whenever he finds it is practicable to use another strain of the same type which is potentially less pathogenic for man, and that it will produce a vaccine of greater safety and of at least equivalent potency.

This regulation's precursor, 42 C.F.R. § 73.110(b), in effect when Lederle was licensed to manufacture the Vaccine, was virtually identical except that under subsection (2), the strain was required to be tested on 100,000 susceptible persons instead of 1 million such persons.

tion as “the boundary between Congress’ willingness to impose tort liability upon the United States and its desire to protect certain governmental activities from exposure to suit by private individuals.” *Id.* at 808. The inquiry in this case centers around whether the government’s alleged failure to follow its own regulatory commands is the type of decision that Congress intended to shield from tort liability in order to preserve a zone within which choice by government personnel can be exercised without threat of suit under the FTCA.

The issue can be stated from the standpoint of those subject to the government. Most governmental action imposes costs and confers benefits on different persons. Regulatory action fits this pattern. The discretionary exception may be said to fix an area within which the burdens of government must be borne by those upon whom they fall. No government can shift all losses. To attempt to do so would only visit greater losses more widely. In a sense the search is for the congressionally designated victims.

Our search must employ the map provided by *Varig*. There the Supreme Court held that the United States was not liable for the negligence of the Federal Aviation Administration (FAA) in certifying certain aircraft for use in commercial aviation. 467 U.S. at 819-21. The FAA has developed a system of spot checking aircraft manufacturers to police compliance with minimum safety standards. *Id.* at 816-19. However, the Court held that the ultimate responsibility of assuring compliance was left with the manufacturer. *See id.* at 821.

In considering the reach of the discretionary function exception, the Court discussed two factors in its analysis. “First, it is the nature of the conduct, rather than the status of the actor, that governs whether the discretionary function exception applies in a given case.” *Id.* at 813. Or,

put another way, “the basic inquiry concerning the application of the discretionary function exception is whether the challenged acts of a Government employee—whatever his or her rank—are of the nature and quality that Congress intended to shield from tort liability.” *Id.*

The second factor was predicated upon the underlying basis for the discretionary function exception. From a review of the legislative history of the exception the Court concluded that, whatever else § 2680(a) may include, “it plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator of the conduct of private individuals.” *Id.* at 813-14. In protecting regulatory activity, “Congress wished to prevent judicial ‘second-guessing’ of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort.” *Id.* at 814.

In deciding *Varig* the Court reaffirmed its decision in *Dalehite v. United States*, 346 U.S. 15 (1953). In *Dalehite*, plaintiffs sued the United States on claims arising from a massive explosion of nitrate fertilizer being exported as a part of a post-World War II United States relief program. *Id.* at 17-19. The plaintiffs claimed that the government had been negligent in adopting the fertilizer program as a whole, in various phases of manufacturing plan, and in policing shipboard loading. *Id.* at 23-24. The Court held that the government’s conduct came within the discretionary function exception. *Id.* at 37-45.

The unanimous Court in *Varig*, although conceding that the Court’s interpretation of the exception since *Dalehite* had not followed a straight line, rejected the suggestion that the view of § 2860(a) expressed in *Dalehite* had been eroded. 467 U.S. at 811-12. Our post-*Varig* decisions have hewed closely to the *Dalehite* and *Varig* views of the discretionary function exception. See *Mitchell v. United States*, 787 F.2d 466 (9th Cir. 1986) (agency’s decision to

rely on FAA recommendations and not mark ground wires protected); *Cunningham v. United States*, 786 F.2d 1445 (9th Cir. 1986) (acts of OSHA inspectors in executing agency directives protected); *Baie v. Secretary of Defense*, 784 F.2d 1375 (9th Cir.) (decision interpreting regulations governing medical benefits for retired military personnel falls within exception), *cert. denied*, 107 S. Ct. 92 (1986); *Proctor v. United States*, 781 F.2d 752 (9th Cir.) (*Varig* extends discretionary function exception to alleged FAA negligence in actual inspection of discrete parts of aircraft), *cert. denied*, 106 S. Ct. 2918 (1986); *Chamberlin v. Isen*, 779 F.2d 522 (9th Cir. 1985) (patent examiner's conduct in rejecting a patent application protected); *Begay v. United States*, 768 F.2d 1059 (9th Cir. 1985) (decision of Public Health Service not to warn miners of radiation dangers protected); *Natural Gas Pipeline Co. of America v. United States*, 742 F.2d 502 (9th Cir. 1984) (*Varig* controls a case of alleged negligence in conducting actual inspections for certification).

However, none of these cases has addressed the precise issue raised here: whether a government agency, when regulating the conduct of private individuals, may be subject to tort liability for the alleged negligence of an agency employee in failing to follow a specific mandatory regulation. The precise failure here was, contrary to the applicable statute, to license a vaccine that had not been tested by its manufacturer in exactly the manner required by HEW's own regulations. The issue this failure poses is a close and difficult one. The discretionary function exception shelters actions taken on the basis of erroneous facts, the failure to exercise available discretion in any way, the failure to perform supervisory tasks, and the failure to enforce effectively regulatory orders. It would not extend this exception greatly to include within it the facts of this case.

We are hesitant to do so, however. Two factors influence us. They are, first, that authorities existing in other circuits point us this way, and, second, the belief that the exception should be applied cautiously in the field of drug and vaccine testing. Turning first to the authorities in other circuits, the Eighth Circuit, prior to *Varig*, reached the precise issue raised here on identical facts in *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981), *cert. denied*, 456 U.S. 944 (1982). The *Loge* court found that the negligent failure of the government to require the mandatory test of 21 C.F.R. § 630.10(b), the regulation in question here, was not protected by the discretionary function exception. *Id.* at 1272-73. In so finding the court stated that “[t]he Secretary has no discretion to disregard the mandatory regulatory commands pertaining to criteria a vaccine must meet before licensing its manufacture or releasing a particular lot of vaccine for distribution to the public.” *Id.* at 1273.

The court in *Loge* relied for its holding on *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974), in which the plaintiff brought an action against the Division of Biological Standards (DBS) alleging that DBS acted negligently in its decision to release a production lot of oral live virus polio vaccine. *Id.* at 1062-63. The Third Circuit, distinguishing the professional discretion involved in approving the vaccine from the discretion involved in the formulation of government policy, held that the claim was not barred by the discretionary function exception. 500 F.2d-at 1066-67. The *Griffin* court stated in dicta, relied upon by the *Loge* court, that even if discretion were otherwise conferred upon DBS, “no discretion was conferred to disregard the mandatory regulatory command.”⁴ *Id.* at 1068.

⁴ In *General Public Utilities Corp. v. United States*, 745 F.2d 239 (3d Cir. 1984), *cert. denied*, 469 U.S. 1228 (1985), the Third Circuit noted that its *Griffin* opinion “must be read cautiously because in

The government, quite understandably, contends that the analysis in *Loge* and *Griffin* has been undercut by the Supreme Court's opinion in *Varig*. To it *Varig* means that whenever an action is based upon regulatory inspection and enforcement activities, the discretionary function exception bars tort claims against the government arising out of those activities. We decline to go that far. The Fifth Circuit has also declined and rejected the "argument that *Varig* exempts the United States from liability whenever challenged conduct is regulatory in nature." *Collins v. United States*, 783 F.2d 1225, 1229 (5th Cir. 1986). The *Collins* court conceded that, after *Varig*, "the United States is not liable for damages based on challenges necessarily directed at an agency's discretion, if it exists, in determining the extent to which it will regulate or the manner in which this will be done, even if the regulations being enforced are mandatory." *Id.* The court, however, found § 2680(a) inapplicable when a federal agency employee refuses to carry out a mandatory statute or regulation. *Id.* at 1231. Until instructed otherwise, we stand alongside the Fifth Circuit.

Varig the discretionary exception covered an agency decision that rested on highly technical information." *Id.* at 246. The court, however, did not determine the continued validity of *Griffin* but simply noted that "pre-*Varig* cases on the discretionary function must be re-evaluated." *Id.* at 246 n.8. The validity of *Griffin* remains an open question in the Third Circuit. See *Smith v. Johns-Manville Corp.*, 795 F.2d 301, 309 n.13 (3d Cir. 1986). The Eleventh Circuit has concluded that *Griffin* is consistent with *Varig*. See *Alabama Elec. Coop., Inc. v. United States*, 769 F.2d 1523, 1529 n.2 (11th Cir. 1985).

The appellants argue that the Third Circuit's uneasiness about *Griffin* should discourage us from following *Loge*, which relied on *Griffin*. However, the controversial part of *Griffin* is its holding that professional and scientific decisions are outside the scope of the discretionary function exception. Its dicta concerning mandatory regulatory commands has not been the subject of attack.

The government argues that the regulatory scheme in this case is similar to the scheme in *Varig*, and that the regulations being enforced in *Varig* were no less mandatory than those at issue here. However, the government overlooks an important distinction. In *Varig* the mandatory regulations governed the conduct of the airline, not the government.⁵ The regulatory scheme granted discretion to the Secretary of Transportation to decide what inspection system to adopt for enforcing the mandatory safety standards. The Court stated that “[w]hen an agency determines the extent to which it will supervise the safety procedures of private individuals, it is exercising discretionary regulatory authority of the most basic kind.” 467 U.S. at 819-20. In this case the Secretary may not issue a license for manufacturing poliovirus vaccine unless the relevant test data has been submitted. See 42 U.S.C. § 262(d); 21 C.F.R. § 630.10(b)(2). Agency employees charged with enforcing poliovirus vaccine safety standards must require the submission of the test data. As to that there is no discretion.

The appellants do not challenge the *promulgation* of regulations governing polio vaccine production. Nor do they challenge *conduct* performed by government employees in accordance with agency directives. They allege a negligent failure to obey a mandatory regulatory command. We are not prepared to hold that § 2680(a) insulates the government from liability under such circumstances.

Our holding that the plaintiffs’ claims are not barred by § 2680(a) does not end the inquiry into whether the Bakers have established a cause of action.⁶ Whether the Bakers

⁵ The regulations specifically required receptacles to be made of fire-resistant material. See *Varig*, 692 F.2d 1205, 1207 (9th Cir. 1982), *rev’d*, 467 U.S. 797 (1984).

⁶ The FICA waives the government’s sovereign immunity in cases “where the United States, if a private person, would be liable to the

have a claim against the government depends on whether a private person under like circumstances could be found liable in tort under applicable state law. The district court made no findings with respect to this local law requirement, and the parties did not brief this issue on appeal. Therefore, we must reverse the district court order granting the government's motion to dismiss and remand for further proceedings consistent with this opinion. On remand, the district court should consider which state's substantive law applies and whether that state provides a cause of action against private parties that is analogous to the claims against the United States here. *See United Scottish Ins. Co.*, 614 F.2d at 198. Should state law fail to provide such a cause of action, the district judge must dismiss the case for failure to state a claim pursuant to the FTCA.

REVERSED AND REMANDED.

claimant in accordance with the law of the place where the act or omission occurred." 28 U.S.C. § 1346(b). It is well established principle that "the existence of a federal statutory duty does not of itself create a duty to be vindicated by the Act." *United Scottish Ins. Co. v. United States*, 614 F.2d 188, 194 n.4 (9th Cir. 1979), *aff'd after remand*, 692 F.2d 1209 (9th Cir. 1982), *rev'd on other grounds*, 467 U.S. 797 (1984); *accord Art Metal-U.S.A., Inc. v. United States*, 753 F.2d 1151, 1157 (D.C. Cir. 1985).

APPENDIX B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

Civil No. 85-0474-T (CM)

WADE BAKER, PLAINTIFF

v.

UNITED STATES OF AMERICA,
AND DOES 1 THROUGH 25, INCLUSIVE, DEFENDANTS

[Filed Dec. 10, 1985]

ORDER GRANTING SUMMARY JUDGMENT

The defendants' Motion to Dismiss or in the Alternative for Summary Judgment came on for hearing on December 9, 1985. The plaintiff was represented by James D. Crosby; and the defendant was represented by Peter K. Nunez, United States Attorney, by and through Karen M. Schichman, Assistant U.S. Attorney. Having duly considered the written and oral arguments of counsel, and finding them to be well founded:

The Court holds that the present case is analogous to *United States v. S.A. Empresa de Viacao Aerea Grandense (Varig Airlines)*, ___ U.S. ___, 104 S.Ct. 2755, 81 L. Ed. 2d 660 (1984), and is therefore barred by the discretionary function exception to the Federal Tort Claims Act, 28 U.S.C. § 2680(a). Accordingly,

IT IS HEREBY ORDERED that the defendant's Motion to Dismiss, or in the Alternative for Summary Judgment be granted.

IT IS FURTHER ORDERED that plaintiff shall have 30 days from the date of the entry of the present order within which to file an amended complaint, should he choose to do so. The failure to file an amended complaint within this time period will result in the dismissal of the present matter without prejudice.

DATED: Dec. 17, 1985

/s/ JOHN S. RHOADES
John S. Rhoades
Judge of the District Court

Presented by:

PETER K. NUNEZ
United States Attorney

/s/ Karen M. Shichman
KAREN M. SCHICHMAN
Assistant U.S. Attorney
Attorney for Defendants

Approved as to form:

/s/ James D. Crosby
JAMES D. CROSBY
Attorney for Plaintiff

APPENDIX C

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

No. 86-5578
DC# CV85-04704-HBT

WADE BAKER, AND RITA BAKER, PLAINTIFFS-APPELLANTS

v.

UNITED STATES OF AMERICA, DEFENDANT-APPELLEE

[Filed Oct. 15, 1987]

ORDER

Before: SNEED and SCHROEDER, Circuit Judges, and
MARQUEZ*, District Judge

The panel as constituted in the above case has voted to deny the petition for rehearing and to reject the suggestion for rehearing en banc.

The full court has been advised of the suggestion for en banc rehearing, and no judge of the court has requested a vote on the suggestion for rehearing en banc. Fed. R. App. P. 35(b).

The petition for rehearing is denied, and the suggestion for a rehearing en banc is rejected.

* Honorable Alfredo C. Marquez, United States District Judge for the District of Arizona, sitting by designation.

